

REMARKS

Claims 1 and 2 are rejected under 35 U.S.C. §102(b) as being anticipated by Rantanen-Lee (U.S. Patent No. 5,035,399) ("Rantanen-Lee"). Claims 1 and 2 are also rejected under 35 U.S.C. §102(b) as being anticipated by Rocco (U.S. Patent No. 4,834,702) ("Rocco"). Each of these grounds of rejection is based on an interpretation of claims 1 and 2 as reading on the clamp disclosed in each of the references.

Applicants respectfully submit that the Office's interpretation of the claims is not reasonable. The Office alleges that the clamp disclosed in each of the references is capable of being placed and used on the tube of a winged needle "and for storing the needle after use." (Action, page 2, lines 8-9, and page 3, lines 3-4). This is not correct unless the wings are removed from the needle and tube prior to storing because in the clamps of the references tube insertion holes are provided in both the proximal and distal sides. The wings cannot slide through the hole on the distal side when it is on the tube.

The Office also states that a clearance is provided between the upper member and lower member of the clamps of the references

"through which at least the wing of a winged needle is capable of being introduced" when the members are not engaged. (Action, page 2, lines 13-14, and page 3, lines 8-9). This interpretation is also not correct because, again, the wings would have to be removed from the needle and the tube of a winged needle to introduce the wings through the clearance.

For the reason that the Office has not given claim 1 its broadest reasonable interpretation, the 35 U.S.C. § 102 rejections are improper, i.e., the claims as properly interpreted do not read on the clamps of the cited references, and should be removed.

Notwithstanding that the claims as originally presented do not read on the cited references, claim 1 has been amended to ensure a proper interpretation. Specifically, claim 1 has been amended to recite the clamp of the present invention, which is placed on the tube of a winged needle and used for storing the needle after use, the winged needle including a needle cannula, a hub with a wing, and a tube connected to the hub, as comprising:

- a proximal side and a distal side;
- a flexible curved portion on the proximal side having a tube insertion hole;

an upper member and lower member connected via said curved portion, the upper member and the lower member being detachably engaged at distal ends thereof so that a clearance is provided between the upper member and the lower member when said members are not engaged through which clearance said hub with a wing of said winged needle is introduced when the clamp is disposed on said tube and said hub with a wing is slid into the clamp;

a pressurizing portion provided on said upper member or lower member for engaging and pressurizing said tube when said members are engaged; and

a space for storing said needle cannula and said hub provided in the upper member or lower member.

The Rantanen-Lee and Rocco references fail to disclose or suggest a clamp having the structural limitations recited in claim 1.

The purpose and the structure of the clamp in the present invention are different from those in the references cited by the Examiner as follows.

Rantanen-Lee describes an apparatus for clamping a tube which effectively and conveniently occludes a length of tubing without damaging the tubing even after repeated application of the clamp. The apparatus of Rantanen-Lee for occluding resilient tubing to

interrupt the flow of a fluid therethrough has a means (110) for protectively covering at least a portion of the circumference of the resilient tubing. The compressive clamp body (102) is jointed to the protective sleeve (110) by an adhesive material represented at (112) (col. 4, lines 45-47). As seen in Fig. 2, the tubing (10) cannot be introduced between the lever end (106) and pawl (104) when the lever end and pawl are disengaged. Consequently, a hub with a wing of a winged needle cannot be introduced through the clearance provided between the lever end (106) and pawl (104) upper when said members are not engaged when the clamp is disposed on said tube and said hub with a wing is slid into the clamp.

The tubing of Rantanen-Lee has no wing and is routed through the apertures provided in clamp body (102) (col. 4, lines 6-9).

Rocco discloses a kidney-ureter catheter assembly for evacuation of crumbled calculi. The catheter comprises a semi-rigid guide element (12) having a substantially cylindrical cross-section and a rounded tip at one end thereof, a semi-rigid intermediate member (4) having a tubular configuration and a first end of a frusto-conical configuration, a flexible tubular catheter (2) and fastening means for detachably fastening the catheter (2)

to the intermediate member (4) when said elements are inserted into each other in the assembled condition (see, claim 1).

The fastening means comprises a spring element (5) (refer to Fig. 4) having a first fastening portion (6) provided with a first gripping area (9), a second fastening portion (7) having a free end which is substantially parallel to the first fastening portion (6) and having a second gripping area (10) facing the first gripping area (9), a spring portion (8) connecting the first and second fastening portions (6, 7) to each other, and a clasping portion (11) (see claim 1).

A first opening (8a) and a second opening (11a) are provided in the clasping portion (11) and spring portion (8), respectively, through which openings spring (5) can be slidably engaged on catheter (2) as shown in Fig. 1 (see, col. 3, lines 30-33).

As with the clamp of Rantanen-Lee, a hub with a wing of a winged needle cannot be introduced through the clearance provided between the upper member (6) and the lower member (7) of the spring element (5) of Rocco when said members are disengaged and when the clamp is disposed on a tube and said hub with a wing is slid into the clamp as required in claim 1.

The catheter (2), the intermediate member (4) and the guide element (12) of the device of Rocco are routed through apertures (11a, 8a) provided in spring (5).

Submitted herewith for the convenience of the Office are drawings illustrating the unobvious differences between the clamp of the present invention and that disclosed in each of the Rantanen-Lee and Rocco patents.

Removal of the 35 U.S.C. § 102 rejections and a formal notice of the allowability of claims 1 and 2 are believed to be in order and are respectfully solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated February 5, 2003, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.


PATENT APPLN. NO. 09/870,583
RESPONSE UNDER 37 C.F.R. §1.111

**PATENT
NON-FINAL**

In the event any additional fees are required, please also
charge our Deposit Account No. 111833.

Respectfully submitted,

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Enclosure: Drawings illustrating differences between clamp of
invention and that of Rantanen-Lee and Rocco